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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,498	02/12/2004	Donald P. Ewing	01113-1-0010	5239

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EXAMINER
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CEGIELNIK, URSZULA M

ART UNIT	PAPER NUMBER
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3711

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/777,498

Applicant(s)

EWING ET AL.

Examiner

Urszula M. Cegielnik

Art Unit

3711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 25-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 02/12/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The applicant's election of Group I without traverse (filed 22 August 2006) is hereby acknowledged. An action on the merits of claims 1-24 follows:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the same housing" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 24, lines 2-3, recites "said electrogel pads are secured to the apparatus by use of a fastening arrangement". Lines 3-4 recite "a male component is located on either the apparatus or a backside of the electrogel pad". It is not clear through this recitation if the male component is located on each of the electrogel pads or the electrogel pads as a unit.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiba et al. (US Patent No. 6,456,885) in view of Michelson et al. (US Patent No. 6,445,955).

Shiba et al. disclose a control circuit (42) connected directly to two or more electrodes (40,41) wherein the control circuit (42) and the electrodes (40,41) are contained within the same housing (col. 5, lines 32-33); wherein the apparatus forms a flexible device that fits close to a body (col. 4, lines 36-40); and wherein the apparatus is attachable to the body with adhesive comprising replaceable electrogel pads (col. 5, lines 1-5); two control switches in the form of knobs (421); the first control switch powers the apparatus on and off and selects an intensity of the stimulation; and the second control switch activating the stimulation.


Shiba et al. do not disclose the control circuit explicitly surrounded by a layer of electrical insulation; the housing formed by one or more layers of water resistant materials (thermoplastic and polyvinyl chloride); the electrodes being in the same housing.

Michelson et al. disclose a housing having a water resistant layer (col. 6, lines 45-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a water resistant layer as taught by Michelson et al., since such a modification would prevent corrosion of components inside the housing from water or sweat.

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With regards to the control circuit surrounded by a layer of electrical insulation, the Examiner takes Official Notice that it is notoriously well known in the electrical engineering art to provide control circuits with a layer of electrical insulation.

With respect to the material of the housing being polyvinyl chloride, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to ~~a~~ have a material for the housing composed of polyvinyl chloride, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. 

With respect to the electrodes being located in the same housing, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the electrodes located in the same housing, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Silverstone (US Patent No. 6,351,674).

Shiba et al., as modified by Michelson et al., lacks an adjustable voltage intensity ranging from 90 to 180 volts.

Silverstone teaches an electrical stimulation device with voltages in the range between 90 and 180 volts (col. 3, lines 19-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed features as taught by Silverstone, since Silverstone states at col. 3, lines 19-20, that such voltages are known of typical stimulators.

Claims 3, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Gilmer et al. (US Patent No. 4,014,323).

Shiba et al., as modified by Michelson et al., lacks an adjustable voltage intensity that includes a low, a medium and a high intensity level.

Gilmer et al. teaches an adjustable voltage intensity that includes a low, a medium and a high intensity level (col. 5, line 68 through col. 6, lines 1-4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Gilmer et al., since Gilmer et al. state at col. 6, lines 7-8 that such a modification would permit adjusting the power until a proper comfort level of electric power intensity is reached.

Claims 5, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Reiss (US Patent No. 5,549,656).

Shiba et al., as modified by Michelson et al., lacks the body receiving approximately 15 to 19.5 volts when the apparatus is attached on the body and low intensity is activated.

Reiss teaches the body receiving 0 to 60 volts (a range in which the claimed values fall within) when the apparatus is attached on the body and the claimed intensity is activated (col. 3, lines 26-27).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Reiss, since such a modification would provide the desired intensity of voltage to be administered.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Beggs (US Patent No. 6,917,293).

Shiba et al., as modified by Michelson et al., lacks the apparatus powered by a 3-volt lithium battery.

Beggs teaches an apparatus powered by a 3-volt lithium battery (col. 14, line 26).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Beggs, since such a medication would provide a power source that is both portable and compact.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Liss et al. (US Patent No. 5,851,223).

Shiba et al., as modified by Michelson et al., lacks the apparatus outputting a square waveform at a constant current.

Liss et al. teach an apparatus outputting a square waveform at a constant current (see Figure 1C, for example).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Liss et al., since such a modification would permit the timing of the control circuitry.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Thomas (US Patent No. 5,107,835),

Shiba et al., as modified by Michelson et al., lacks the apparatus using a frequency of approximately 0.1 to 4000 Hertz.

Thomas teaches an apparatus using a frequency of approximately 0.1 to 4000 Hertz (col. 2, lines 19-25).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Thomas, since Thomas states at col. 2, lines 19-20 that such a modification would decrease inflammation in an afflicted region in a patient.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of DiLorenzo (US Patent Application Publication No. 2003/0018367).

Shiba et al., as modified by Michelson et al., lacks the apparatus having a pulse width of approximately 45 milliseconds and a range from .01 microsecond to 50 milliseconds.



DiLorenzo teaches an apparatus having a pulse width in the range of 1 microsecond and 1000 milliseconds (paragraph 0100, lines 8-10).

With regards to providing a pulse width from the range of .01 microsecond, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a pulse width from the range of .01 microsecond, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 333.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Zilber (US Patent No. 3,822,708),

Shiba et al., as modified by Michelson et al., lacks the apparatus outputting approximately thirty pulses over a four second duration.

Zilber teaches an apparatus outputting 5 to 200 pulses per second (col. 4, line 9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Zilber, since such a modification would permit a certain value of current to be passed.

With regards to providing the time period being four seconds, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a time period being four seconds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 333.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Yamazaki et al. (US Patent Application Publication No. 2003/0153958).

Shiba et al., as modified by Michelson et al., lacks the apparatus including Yamazaki et al. teach an apparatus having at least two buttons, the first button (12) powers the apparatus on and off and selects an intensity of the stimulation and the second button (14) activates the stimulation (paragraphs 0058, 0070, 0071).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed features as taught by Yamazaki et al., since such a medication would permit the user to tailor the amount of stimulation that is desired.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Grey et al. (US Patent No. 5,397,338).

Shiba et al., as modified by Michelson et al., lacks the apparatus including indicators that display the status and intensity of the stimulations.

Grey et al. teach an apparatus including indicators that display the status (i.e. mode) and intensity of the stimulations (col. 7, lines 51-53 and 55-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed features as taught by Grey et al., since such a modification would permit the user to administer the type and intensity of stimulation desired.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Ceballos et al. (US Patent No. 6,522,915).

Shiba et al., as modified by Michelson et al., lacks the electrogel pads being composed of hydrogel.

Ceballos et al. teach electrode surfaces being composed of hydrogel (col. 5, lines 51-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Ceballos et al., since Ceballos et al. state at col. 5, lines 56-59 that such a modification would protect the electrode surfaces from damage during handling and prevent contamination.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Agarwal et al. (US Patent Application Publication No. 2004/0116990).

Shiba et al., as modified by Michelson et al., lacks the electrogel pads secured to the apparatus by use of a fastening arrangement where a male component is located on a backside of an electrogel pad and couples with a female component which is located on the backside of an electrogel pad.

Agarwal et al. teaches pads that have a fastening mechanism on a surface composed of a hook and loop fastener (paragraph 0042, lines 1-13).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Agarwal et al., since such a modification would permit the pads to be positively secured.


### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urszula M. Cegielnik whose telephone number is 571-272-4420. The examiner can normally be reached on Monday through Friday, from 5:45AM-2:15PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eugene L. Kim can be reached on 571-272-4463. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Umc

  
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SUPERVISORY PATENT EXAMINER